

REMARKS

Claims 1-25 are pending in the instant application. Claims 20 and 25-50 have been canceled herein. Claims 1, 21, and 22 have been amended herein. Support for these amendments can be found throughout the specification and originally filed claims. New claim 51 has been added. Support for new claim 51 can be found, for example, in the specification at page 10, line 28 through page 11, line 3. No new matter has been added.

Rejection under 35 U.S.C. § 112, first paragraph

Claims 1-25 were rejected under 35 U.S.C. §112, first paragraph for not being enabled for preventing bacterial gastrointestinal infection. Claims 20 and 25 have been canceled herein. Thus, this rejection, as it applies to these claims, is moot and should be withdrawn. The Examiner indicates that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. (*See* Office action at page 4.) The Examiner further states that the specification as-filed fails to enable the full scope of the “preventing” language, which requires prevention of any and all infections in the gastrointestinal tract, and in every instance. According to the Examiner, undue experimentation would be required to practice the full scope of the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). (*See* Office action at page 5.)

To address this rejection, independent claim 1 has been amended herein to specify a method of treating a bacterial gastrointestinal infection in a human selected from the group consisting of, *Clostridium perfringens*, *Clostridium difficile*, *Clostridium botulinum*, *Clostridium tributrycum*, *Clostridium sporogenes*, *Escherichia coli*, *Pseudomonas aeruginosa* and *Staphylococcus aureus*. According to the Examiner, claims 1-25 are enabled for treating bacterial gastrointestinal infections. (*See* Office action at page 4.) Moreover, the as-filed specification discloses the use of *Bacillus coagulans* to inhibit the growth of *Clostridium perfringens*, *Clostridium difficile*, *Clostridium botulinum*, *Clostridium tributrycum*, *Clostridium*

sporogenes, *Escherichia coli*, *Pseudomonas aeruginosa* and *Staphylococcus aureus*. (See, e.g., Example 4, pages 27-28.) Thus, Applicants submit that one of ordinary skill in the art would be able to use the claimed method without undue experimentation and with reasonable expectation of success.

Rejection under 35 U.S.C. §102

Claims 12 and 13 were rejected under 35 U.S.C. §102(e) as being anticipated by Cavadini, et al (US Patent Number 5,968,569). The Examiner states that Cavadini discloses the preparation of cereal type products, including infant cereals, and pet food, which contain probiotic microorganisms such as *B. coagulans*, and which may contain fructooligosaccharides as a soluble fiber component. (See Office action at page 6.) The probiotic is in the form of a coating, filling or flakes of gelatinized starch matrix. According to the Examiner, because Cavadini discloses administering the claimed ingredients in the treatment of diseases encompassed by the claims, a holding of anticipation is required.

To address this rejection, claim 1 has been amended to specify a method of treating a bacterial gastrointestinal infection in a human comprising orally administering to a human subject a composition comprising viable colony forming units (CFU) of a non-pathogenic lactic acid bacteria, wherein the composition is an oral electrolyte maintenance formulation. Cavadini teaches the preparation of cereal compositions, which contain probiotic microorganisms as a filler or coating, (See, Cavadini, column 1, lines 64-67 and column 2, lines 26-31.) but fails to describe an oral electrolyte formulation. Therefore, Cavadini does not teach all of the limitations of claim 1. Thus, claim 1 is not anticipated by Cavadini. Claims 2-19 and 21-24 depend, directly or indirectly, on claim 1, and, therefore, contain all of the limitations of that claim. Thus, these claims are also not anticipated by Cavadini. For these reasons, Applicants request withdrawal of the rejection.

Rejection under 35 U.S.C. §103

Claims 12-18 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Cavadini, *et al.* (US Patent Number 5,968,569). According to the Examiner, even if one of ordinary skill in the art did not immediately envisage the claimed treatment method from Cavadini's disclosure, Cavadini clearly provides motivation for practicing the subject matter

recited in claims 12 and 13 by disclosing that the claimed ingredients were suitable methods of treating the claimed disorder. (*See* Office Action at pages 7-8.) The Examiner states that Cavadini differs from the claims in that Cavadini does not disclose the specific polymer length of the fructooligosaccharides administered therein, nor does Cavadini disclose administration of the specific dosages recited in the claims. The Examiner further states that the artisan of ordinary skill at the time of Applicant's invention clearly would have recognized that by varying the dose of the fiber component used in the therapeutic methods of Cavadini, one would have affected the result of the therapeutic methods.

As discussed above, Applicants note that claim 1 has been amended to specify a method of treating a bacterial gastrointestinal infection in a human comprising orally administering to a human subject a composition comprising viable colony forming units (CFU) of a non-pathogenic lactic acid bacteria, wherein the composition is an oral electrolyte maintenance formulation. In contrast, Cavadini teaches cereal products that are coated or filled with a gelatinized starch matrix containing a probiotic microorganism. (*See* Cavadini, column 2, lines 12-13.) For these reasons, Applicants request withdrawal of the rejection.

Double Patenting

Claims 1-11 and 19-25 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13 and 14 of US Patent Number 6,461,607, and claims 1-10 of US Patent Number 6,849,256.

In response, Applicants submit herewith terminal disclaimers in compliance with 37 C.F.R. § 1.321 (c) along with the appropriate fees. Thus, this rejection is now moot and should be withdrawn.

Claims 12-18 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13 and 14 of US Patent Number 6,461,607 and claims 1-10 of US Patent Number 6,849,256, in view of Cavadini *et al.* (US Patent Number 5,968,569).

As mentioned above, Applicants submit herewith terminal disclaimers in compliance with 37 C.F.R. § 1.321 (c) along with the appropriate fees. Thus, this rejection is moot and should be withdrawn.

Claims 1-11 and 19-25 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 25-35 of copending application number 11/005,897.

In response to the April 6, 2006 Restriction Requirement of copending application serial number 11/005,897, Applicants elected the invention of Group I, claims 1-5, 7-11, 13-16, and 19-22, drawn to a composition comprising an isolated *Bacillus* strain, classified in class 435, subclass 252.5. Thus, claims 25-35 of copending application serial number 11/005,897 have been canceled. Applicants submit that claims 1-11 and 19-25 of the instant application should not be rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 25-35 of copending application serial number 11/005,897. This rejection should be withdrawn.

Claims 12-18 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 25-35 of copending application serial number 11/005,897 in view of Cavadini *et al* (US Patent Number 5,968,569). However, as discussed above, claims 25-35 of copending application serial number 11/005,897 have been canceled. Thus, Applicants submit that claims 1-11 and 19-25 of the instant application should not be rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 25-35 of copending application serial number 11/005,897 in view of Cavadini *et al*. This rejection should be withdrawn.

CONCLUSION

On the basis of the foregoing amendments, Applicants respectfully submit that the pending claims are in condition for allowance. If there are any questions regarding these amendments and remarks, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,



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